

K962527

**AUG - 1 1996**

(I) **510(k) Summary:**

This summary is submitted in conformance with the format described in the 21 CFR Part 807.92 interim rule dated April 28, 1992.

(1) **Submitted By:**

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**Contact Person:**

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(2) **Name of Device:**

General Purpose Dental Tray

**Classification Name:**

Unknown

(3) **Identification of Predicate Devices:**

Sterile Dental Systems, Inc.  
Operative Pack

Sterile Concepts  
Richmond, VA 23234

**(4) Description of Device Subject to Premarket Notification:**

The General Purpose Dental Tray is intended to conveniently provide the auxiliary components utilized during general dental procedures. The components are items that are commonly used during a variety of dental procedures. The general Purpose Dental Tray provides the convenience of having these commonly used items packaged in a single package, sterile, and ready to use. The kits are provided sterile, disposable, and for single patient use.

**(5) Intended Use of the Device:**

The General Purpose Dental Tray is a single patient, single use, disposable device which is intended to conveniently provide general use auxiliary components for the administration of dental procedures.

**(6) Technological Characteristics**

The MedCare General Purpose Dental Tray is similar to the predicate device in that both of the device provide a variety of auxiliary components for the convenient administration of dental procedures. Both devices provide flexibility in componentry selection for kit customization , which provides the maximum convenience for the customer.